**PACKAGE LEAFLET: INFORMATION FOR THE USER**

# Diclofenac Sodium 25 mg Gastro-resistant Tablets
# Diclofenac Sodium 50 mg Gastro-resistant Tablets
(diclofenac)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**
1. What Diclofenac Sodium Tablets are and what they are used for
2. What you need to know before you take Diclofenac Sodium Tablets
3. How to take Diclofenac Sodium Tablets
4. Possible side effects
5. How to store Diclofenac Sodium Tablets
6. Contents of the pack and other information

## 1. What Diclofenac Sodium Tablets are and what they are used for

Diclofenac sodium, the active ingredient in Diclofenac Sodium Tablets, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.
Diclofenac Sodium Tablets relieves pain, reduces swelling and eases inflammation in conditions affecting the joints, muscles and tendons including:
- Rheumatoid arthritis, osteoarthritis, acute gout, low back pain, ankylosing spondylitis
- Backache conditions affecting the joints and muscles such as sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations and fractures
- Conditions affecting the tendons for example, Tendonitis, tenosynovitis, bursitis.

They are also used to treat pain and inflammation associated with orthopaedic, dental and minor surgery.
In children aged 9 years and above, Diclofenac Sodium 25 mg tablets are used for short term treatment of fever and pain related to inflammatory infections of ear, nose and throat (e.g. pharyngotonsillitis, otitis media) and relief of acute postoperative pain.
Diclofenac sodium 50 mg tablets are not recommended for use in children.

## 2. What you need to know before you take Diclofenac Sodium tablets

**Do not take Diclofenac Sodium Tablets if:**
- you are allergic to Diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of this medicine (listed in section 6). Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction
- you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)
- you have severe heart, kidney or liver failure
- you are more than six months pregnant
- you have had stomach or bowel problems after you have taken other NSAIDs
- you have established heart disease and /or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- you have or have had problems with your blood circulation (peripheral arterial disease)

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Diclofenac Sodium Tablets if you:
- suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease (this includes abdominal pain, diarrhoea, vomiting or weight loss)
- have kidney or liver problems, or you are elderly
- have a condition called porphyria (this includes abdominal pain, vomiting, neuropathy and mental disturbances)
- suffer from any blood or bleeding disorder. If you do, your doctor may ask you to go for regular check-ups while you are taking these tablets.
- ever had asthma
- are breast-feeding
- have heart problems, or previous stroke, or think that you might be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- have Lupus (SLE) or any similar condition
- smoke, have diabetes
- have angina, blood clots, high blood pressure, raised cholesterol or abnormally high levels of fat in your blood (raised cholesterol or raised triglycerides)
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Diclofenac Sodium or other pain medications.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

**Other medicines and Diclofenac Sodium Tablets**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist if you are taking:
- Medicines to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin)
- Diuretics (water tablets)
- Lithium (used to treat some mental problems)
- Methotrexate (for some inflammatory diseases and some cancers)
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants)
- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibiotics (for infections)
- Any other NSAID or COX-2 (cyclo-oxgenase-2) inhibitor, for example aspirin or ibuprofen
- Mifepristone (a medicine used to terminate pregnancy)
- Cardiac glycosides (for example digoxin), used to treat heart problems
- Medicines known as SSRIs used to treat depression
- Oral steroids (an anti-inflammatory drug)
- Medicines used to treat heart conditions or high blood pressure, for example betablockers or ACE inhibitors.
- Sulfinpyrazone (a medicine used to treat gout) or voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures)
- Colestipol/cholestyramine (used to lower cholesterol)

Always tell your doctor or pharmacist about all the medicines you are taking. This means medicines you have bought yourself as well as medicines on prescription from your doctor.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking diclofenac tablets, as this medicine can sometimes worsen wound healing in your gut after surgery.

**Pregnancy, breast feeding and fertility**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- Do not take diclofenac sodium if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take diclofenac sodium during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, diclofenac sodium can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.
- Taking Diclofenac Sodium Tablets may make it more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

**Driving and using machines**
Very occasionally people have reported that Diclofenac Sodium Tablets have made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way, you should not drive or operate machinery.

**Diclofenac Sodium Tablets contains**
- Lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Sunset yellow FCF (E110) which may cause allergic reactions.

**Information on sodium content**
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

**Other special warnings**
- You should take the lowest dose of Diclofenac Sodium Tablets for the shortest possible time, particularly if you are underweight or elderly.
- Medicines such as Diclofenac Sodium Tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. This risk is more likely with high doses and prolonged treatment. Always follow the doctor's instructions on how much to take and how long to take it for. If at any time while taking Diclofenac you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately.
- Whilst you are taking these medicines your doctor may want to give you a check-up from time to time.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- Because it is an anti-inflammatory medicine, Diclofenac Sodium Tablets may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Diclofenac Sodium Tablets.
- The 50 mg tablets are not suitable for use in children.

## 3. How to take Diclofenac Sodium Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Keep taking your tablets for as long as you have been told, unless you have any problems. In that case, check with your doctor.
Take the tablets before or with food. Swallow the tablets whole with a drink of water. Do not crush or chew the tablets.

**The usual doses are:**
**Adults**
75 mg to 150 mg daily divided into two or three doses. The number of tablets which you take will depend on the strength the doctor has given you.

Elderly
Your doctor may advise you to take a dose that is lower than the usual adult dose if you are elderly. Your doctor may also want to check closely that the Diclofenac Sodium Tablets are not affecting your stomach.

**Children aged 9-12 years (min 35 kg body weight):**
25 mg tablet only: Doses vary with the age and weight of the child. The usual dose is 2 mg/kg body weight per day in three divided doses.
50 mg tablet is not recommended for use in children.
The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly if you have had stomach problems before, or if you are elderly, or taking certain other drugs as well.

**If you take more Diclofenac Sodium Tablets than you should**
If you, or anyone else, accidentally takes too much, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.



SAME SIZE ARTWORK
560 x 230 mm
Front

**If you forget to take Diclofenac Sodium Tablets**
If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, though, just take the next dose and forget about the one you missed. Do not take a double dose to make up for a forgotten dose. Do not take more than 150 mg (three 50 mg tablets or six 25 mg tablets) in 24 hours.

If you have any further questions on the use of this medicine, ask your doctor, or pharmacist or nurse.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects may be minimised by using the lowest effective dose for the shortest duration necessary. If you suffer from any of the following rare, or very rare, side effects at any time during your treatment, STOP TAKING the medicine and seek immediate medical help:
- Sudden and crushing chest pain (signs of myocardial infarction or heart attack)
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)
- Sudden weakness or numbness in the face, arm or leg especially on one side of the body; sudden loss or disturbance of vision; sudden difficulty in speaking or ability to understand speech; sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These symptoms can be an early sign of a stroke.
- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering
- Wheezing or shortness of breath (bronchospasm)
- Swollen face, lips, hands or fingers
- Yellowing of your skin or the whites of your eyes
- Persistent sore throat or high temperature
- serious illness with blistering of the skin, mouth. eyes and genitals (Stevens-Johnson Syndrome and Toxic epidermal necrolysis) which may be made worse by exposure to sunlight.
- an unexpected change in the amount of urine produced and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Diclofenac Sodium Tablets and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain (frequency not known, cannot be estimated from the available data).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- A serious allergic skin reaction which may include large widespread red and/or dark patches, swelling of the skin, blisters, and itching (Generalised bullous fixed drug eruption).

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

**Tell your doctor if you experience any of the following symptoms:**
**Common (may affect up to 1 in 10 people)**
- headache, vertigo
- feeling, or being, sick
- diarrhoea
- Stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind
- Skin rash or spots
- Raised levels of liver enzymes in blood
- anorexia
- dizziness or feeling light-headed

**Uncommon (may affect up to 1 in 100 people)**
- Fast or irregular heart beat (palpitations), chest pain, heart disorders, including heart attack or breathlessness, difficulty breathing when lying down, or swelling of the feet or legs (signs of heart failure), especially if you have been taking a higher dose (150 mg per day) for a long period of time.

**Rare (may affect up to 1 in 1,000 people)**
- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly)
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Vomiting blood
- Diarrhoea with blood in it or bleeding from the back passage
- Black, tarry faeces or stools
- Drowsiness, tiredness
- Skin rash and itching
- Fluid retention, symptoms of which include swollen ankles
- Liver function disorders, including hepatitis and jaundice
- Asthma (symptoms may include wheezing, breathlessness, coughing and a tightness across the chest).

**Very Rare (may affect up to 1 in 10,000 people)**
Effects on the nervous system:
Inflammation of the lining of the brain (meningitis), tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, taste changes, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, irritability, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck.
Effects on the stomach and digestive system:
Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease), inflammation of the pancreas.
Effects on the chest or blood:
Hypertension (high blood pressure), hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), blood disorders (including anaemia).
Effects on the liver or kidneys:
Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine.
Effects on skin or hair:
Facial swelling, serious skin rashes including Stevens-Johnson syndrome and Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight. Hair loss.
Effects on the reproductive system:
Impotence.

**Not known (Frequency cannot be estimated from the available data)**
- Throat disorders
- malaise (general feeling of discomfort)
- inflammation of the nerves in the eye
- confusion
- hallucinations
- disturbances of sensation.
- An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again.

Medicines such as Diclofenac sodium tablets may be associated with a small increased risk of heart attack or stroke.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow card in the Google Play or Apple App store. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Diclofenac Sodium Tablets

- Keep this medicine out of the sight and reach of children
- Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in a dry place.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Diclofenac Sodium Tablets contains**
The active substance is diclofenac sodium. Each tablet contains either 25 mg (milligrams) or 50 mg of diclofenac sodium.
The other ingredients are anhydrous lactose, microcrystalline cellulose, maize starch, magnesium stearate, colloidal silicon dioxide, methylpropyl hydroxy cellulose phthalate, dibutyl phthalate, talc, Opaspray Orange ((K-1R- 2433) contains E110 (sunset yellow FCF) and E171 (Titanium dioxide)), ethanol denatured with acetone, polyethylene glycol 6000.

**What Diclofenac Sodium Tablets looks like and contents of the pack**
- Diclofenac sodium tablets are orange round tablets marked 'BL' on one side and '25' on the reverse for the 25 mg strength and 'BL' on one side and '50' on the reverse for 50 mg strength.
- Diclofenac sodium tablets come in blister packs containing 28, 84 or 100 tablets and securitainers containing 100 tablets.
- Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
Name and address: Bristol Laboratories Ltd,
Unit 3, Canalside, Northbridge Road,
Berkhamsted, Hertfordshire, HP4 1EG, UK
Telephone: 0044 (0)1442 200922
Email: info@bristol-labs.co.uk

**Diclofenac Sodium 25 mg Gastro-resistant Tablets; PL 17907/0343**
**Diclofenac Sodium 50 mg Gastro-resistant Tablets; PL 17907/0344**

**This leaflet was last revised in August 2025**

To request a copy of this leaflet in Braille, large print or audio format, please contact the licence holder at the address (or telephone, email) above.

V13 05-08-25 D0

XXXXX